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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/963,950 | 09/26/2001 | Gavriel Meron | P-3571-US | 9876 |

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EITAN, PEARL, LATZER & COHEN ZEDEK LLP
10 ROCKEFELLER PLAZA, SUITE 1001
NEW YORK, NY 10020

EXAMINER

NASSER, ROBERT L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3736 | 8 |

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/963,950 | MERON ET AL. |
| Examiner | Art Unit | |
| Robert L. Nasser | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 August 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7,9-15,17-21,23-28 and 30-69 is/are pending in the application.
- 4a) Of the above claim(s) 41-46 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7,9-15,17-28, 30-40 and 47--69 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Applicant's election with traverse of Species II in Paper No. 7 is acknowledged.

The traversal is on the ground(s) that there are claims generic to both species I and II.

This is not found persuasive because the presence of a generic claim does not make an election requirement improper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 41-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the anchoring means of claims 18, 38, and 40 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52, 59, 61, 62, and 69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure only recites monitoring the gastro-intestinal tract. It does not recite immobilizing the device in the small intestine. Therefore, these new claims introduce new matter. Clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 is rejected in that there is no antecedent basis for the means for anchoring.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7, 9, 11, 12, 18-20, 23, 24, 26-28, 30, 32-34, and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Iddan et al. Iddan et al shows an image sensor 118, a transmitter 28, a battery 29 inside a capsule. The capsule is

“capable of being immobilized.” The examiner notes that Iddan et al does not teach actually immobilizing the capsule, but the examiner notes that the claim only requires that the capsule be capable of being immobilized. If applicant were to amend the claim to recite the structure to allow the housing to be immobilized, it would overcome this rejection. The system of Iddan further has an external receiver and display (see figure 1).

Claims 1, 4-7, 9, 11, 12, 13, 17-21, 23, 26-28, 30, 32-35, 38-40, 47-51, 53-58, 60 67, and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Swain et al WO 98/11816. Swain et al has an implantable image sensor including an imaging sensor (44, 46, and 48), a battery 52 or an externally engageable power source (see column 6) and a wireless transmitter 54. It further notes in column 6, lines 18-24 that it has a loop for sewing it into the tissue to immobilize the capsule 42 and 40. With respect to claims 18 and 38, the anchoring means is the thread. Swain further has an external receiver and display for displaying the image data. The examiner notes that immobilizing the device requires some surgical procedure and hence the immobilization occurs during surgery.

Claims 1, 2, 4-7, 11-13, 17-19, 21, 23, 24, 26-28, 32-35, 38-40, 47, 48, 50, 51, 53-54 and 63-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Kilcoyne et al. Kilcoyne shows an implantable housing 18, including a sensor 110 which can be any known biomedical sensor, a rf transmitter 112 for transmitting data to an external receiver and monitor, and a battery 114. The device is immobilized in place using a tread through loop 112, or other attachment means (see column 7, lines 34-45).

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Kilcoyne further teaches the recited method. With respect to claims 63-65, the examiner notes that the immobilizing step is surgery.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Sohrab. Sohrab shows an analyte monitoring device that varies the frequency of measurement based on the analyte levels measured, to avoid unnecessary measurements. . Hence, it would have been obvious to modify Kilcoyne et al to vary to measurement frequency based on the measured data (i.e. there would be a controller that controls the measurement), to use the device as efficiently as possible.

Claims 9, 20, 30, 49, 66, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Swain et al. With respect to claims 9, 20, 30, and 49, Kilcoyne states other types of sensors used in the body can be substituted for the ph sensor 110. Swain et al shows an identical device to Kovacs that images the area of interest. As such, it would have been obvious to modify Kilcoyne et al to use an image sensor, as it is merely the substitution of one known equivalent sensor for another. In addition, with respect to claim 67 and 68, Swain et al teaches the equivalence of a battery and a external engageable power source. Hence, it would

have been obvious to modify Kilcoyne to use an externally engageable power source, as it is merely the substitution of one known equivalent sensor for another.

Claims 10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Fiddian –Green. Fiddian-Green shows a pH sensor whose optical characteristic change in response to pH. It would have been obvious to modify Kilcoyne et al to use such a sensor, as it is merely the substitution of one known pH sensor for another.

Claims 14, 15, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al. Kilcoyne et al shows a device that is sewn into the digestive tract. It does not have the same structure recited in these claims. The examiner notes that the exact structure for engaging the sutures does not solve a stated purpose and is not for a specific reason. As such, the exact structure would have been a mere matter of obvious design choice for one skilled in the art.

Claims 14, 15, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swain et al et al. Swain et al shows a device that is sewn into the digestive tract. It does not have the same structure recited in these claims. The examiner notes that the exact structure for engaging the sutures does not solve a stated purpose and is not for a specific reason. As such, the exact structure would have been a mere matter of obvious design choice for one skilled in the art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

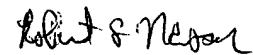
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Selmon et al shows in figure 9 an imaging catheter with suction cups for immobilizing it in vivo.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN

September 22, 2003

ROBERT L. NASSER
PRIMARY EXAMINEP